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75	90 06/22/2006		EXAMINER	
Peter C Knops			ROGERS, DAVID A	
Lathrop & Gage 2345 Grand Boulevard Suite 2800 Kansas City, MO 64108			ART UNIT	PAPER NUMBER
			2856	
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	09/806,274	BEIMESCH, WAYNE EDWARD			
Office Action Summary	Examiner	Art Unit			
	David A. Rogers	2856			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	lely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
Responsive to communication(s) filed on <u>04 Not</u> This action is FINAL . 2b)⊠ This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ⊠ Claim(s) 1-10 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1-10 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or	vn from consideration.				
Application Papers					
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correct and the contract of the contract	epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:				

DETAILED ACTION

- 1. In view of the Appeal Brief filed on 04 November 2005 and the conflicting claims in copending application 10/724,564, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below. To avoid abandonment of the application, appellant must exercise one of the following two options:
- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

- 3. Claims 1-3 and 6 of this application conflict with claims 11-13 of Application No. 10/724,564. In 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.
- 4. Claims 8-10 of this application conflict with claims 23-31 of Application No. 10/724,564. In 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822. Furthermore, the claims intended use for sampling material from a process system is not afforded any patentable weight since the sampled material does not alter the structure of the kit; i.e., the bag does not change simply because of the source of the material placed inside.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly. Failure to comply with this requirement will result in a holding of abandonment of this application.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 4,930,906 to Hemphill.

Claims 8-10 recite two elements that form the kit, namely an enclosed bag that is sealable to produce a headspace and a list of instructions for how to use the sealable bag. In this regard Hemphill teaches an enclosed bag (reference item 10) and having instructions (reference items 18 and 20). The enclosed bag also has a maximum fill line (reference item 19). This bag, when sealed, would have a headspace above the maximum fill line. In claims 32-34 the applicant's bag is further limited to having an inner aluminum layer and an

outer polymeric layer. As seen in figure 5 the bag of Hemphill comprises an aluminum inner layer (reference item 13) and a polymeric intermediate layer (reference item 11). Therefore, Hemphill teaches a kit that meets the structural limitations of the applicant's claims. Hemphill does not teach specific instructions with regard to sampling and analyzing.

In their precedential decision *In re Ngai*, 70 USPQ 2d 1862, the Court of Appeals for the Federal Circuit (CAFC) reviewed a situation clearly analogous to the applicant's claims. In Ngai *et al.* a kit was claimed was claimed as follows (emphasis added):

19. <u>A kit</u> for normalizing and amplifying an RNA population, <u>said kit comprising</u> <u>instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of</u>: oligo dT biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, Rnase H, DNA pol I, <u>buffers</u> and nucleotides.

The CAFC analyzed Ngai et al.'s claim 19 and determined that the elements that formed the kit included a premeasured portion of reagent and instructions on how to use the reagent. The cited prior art was a kit having a 10X buffer and specific instructions on how to use the 10X buffer. In referring to *In re Gulack*, 703 F.2d 1381 [217 USPQ 401] (Fed. Cir. 1983), the CAFC stated:

"This case [Ngai], however, is dissimilar from Gulack. There the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for "educational and recreational mathematical" purposes. Here, addition of a new set of instructions into a known kit does not interrelate with the kit in the same way as the numbers interrelated with the band. In Gulack, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product. As the Gulack court pointed out, "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." Id. If we were to adopt Ngai's position, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product."

The CAFC affirmed the Board of Patent Appeals and Interferences (BPAI) and concluded that Ngai et al.'s claimed kit was anticipated by the prior art (the 10X buffer with instructions), despite the fact that Ngai et al.'s claim 1 method was distinct from the instructions in the prior art. In fact, the method of claim 1 was determined to be patentable over the prior art. The CAFC further concluded that Ngai et al.'s instructions merely taught how to use the reagent component of the kit (the 10X buffer). Specifically, the CAFC concluded:

"All that the printed matter does is teach a new use for an existing product."

and

"He [Ngal] is not, however, entitled to patent a known product by simply attaching a set of instructions to that product."

In the present application the instructions merely teach a different use for a known sealable bag. The applicant's claimed enclosed bag does not depend on the claimed instructions in order to function; i.e., the instructions do not enable the bag to hold a sample. Likewise, the claimed instructions do not depend on the bag in order to instruct someone how to sample. Therefore, the applicant's instructions do not enable any sealable bag from holding any material and only describe a process to store a sample in the bag and then to sample the headspace of the bag.

The applicant's claims for a kit comprising a bag and instructions to use the bag is clearly analogous to Ngai *et al.*'s kit having a known reagent (the 10X buffer) and instructions that taught how to use the reagent. The applicant's arguments with regard to how their instructions are not taught by the prior art,

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and, therefore, there can be no anticipation are also similar to those proffered by Ngai *et al.* However, both the BPAI and the CAFC unequivocally and unambiguously disagreed with that argument.

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Based on the fact that the applicant's kit is known in the art as evidenced by Hemphill, and further because of the CAFC's decision in *In re Ngai*, the applicant's claimed kit is clearly anticipated under 35 USC 102(b).

Furthermore, the intended use of claims 8-10; e.g., for measuring the volatile organic compounds of a material produced in a process, is not being afforded any patentable weight. The intended use of the kit does not patently distinguish the applicant's claims over the prior art. As the applicant is fully aware a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the present application the prior art bags are fully capable of holding materials from a fluid bed dryer, a spray bed dryer, or a storage tank.

Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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8. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art in view of United States Patent 5,140,845 to Robbins, United States Patent 5,809,664 to Legros *et al.*, Chemical Principles" to Masterton *et al.*, and "Compilation of Air Pollutant Emission Factors, AP-42" to the Environmental Protection Agency (EPA), hereinafter referred to as EPA Method AP-42.

The applicant admits that monitoring and controlling volatile organic compound (VOC) emissions is known. More specifically, the applicant states (emphasis added):

A long-standing problem in the chemically-related manufacturing industry has been the way in which the rate of VOC emissions is controlled and monitored. The concerns associated with VOC control and monitoring are well rooted in governmental policies throughout the world, all of which are aimed at reducing the emission of such VOCs into the atmosphere. Additionally, the manufacturing industries themselves have been notably concerned with safety and environmental concerns associated with VOC emissions. As a result, since the onset of the industrial revolution, the chemically-related manufacturing industry has striven for zero to minimal VOC emissions. To that end, relatively expensive and time-consuming VOC measurement techniques have been developed and have been constantly employed to monitor VOC emissions of virtually every unit operation in every manufacturing facility throughout the world. numerous companies have sprouted into existence which specialize in testing techniques for VOCs and aid in ensuring compliance with specific strict company as well as governmental regulations. Such specialization and expertise render these services extremely expensive, and therefore, significantly add to the overall expense of whatever product is being manufactured. Accordingly, there remains a need in the art for an inexpensive, less time-consuming, method by which VOCs can be conveniently measured for a given material being produced in a process system.

The admitted prior art teaches that virtually every unit operation in every manufacturing facility throughout the world monitors for VOC emissions. There is no express mention in the admission for monitoring and/or sampling from a fluid bed dryer, a spray bed dryer, or a storage tank. The admitted prior art also does not teach holding the sampled material at a mean exit temperature of the emissions of a process system.

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With regard to the first issue it is noted that Legros et al. teaches that known that fluid bed dryers can operate up to 400 °C and are a known source of VOCs.

With regard to the second issue Robbins teaches a simple, low cost process for sampling and detecting VOCs. In particular Robbins teaches a process of sampling material from a system, storing the sample in an enclosed bag, sealing the bag, storing the bag until equilibrium is reached in the headspace, and then sampling the headspace in order to determine if VOCs are present. This detection is accomplished using a flame ionization detector (FID). It is known that gas chromatographs and FIDs are used to determine analyte quantities in the sample based on the peak value; i.e., the measured response of the GC/FID. Robbins does not expressly teach a method wherein the sampled material is stored at the mean exit temperature of said emissions of said system.

Masterton et al. is cited herein to provide support of the commonly known scientific principles of liquid-vapor headspace equilibrium in a closed system. In Masterton et al. a sealed flask is used, however the scientific principles apply equally to a sealed bag. Masterton et al. teaches that a liquid placed in the closed system will, over time, reach a state of equilibrium with regard to the headspace. Equilibrium is the state wherein, at any given temperature, the number of molecules from the liquid entering into the vapor state (into the headspace) equals the number of molecules reentering the liquid state. At higher temperatures a larger fraction of molecules will acquire

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enough energy to escape from the liquid to the vapor. This means that at higher temperatures more vapor molecules will be present in the headspace than at lower temperatures. Over time a state of headspace equilibrium will be reached. It is just that more molecules will be present in the vapor when equilibrium is reached using higher temperatures.

Furthermore, EPA Method AP-42, §6.8.3.1, states (emphasis added):

The main atmospheric pollution problem in soap manufacturing is odor. The storage and handling of liquid ingredients (including sulfonic acids and salts) and sulfates are some of the sources of this odor. <u>Vent lines, vacuum exhausts, raw material and product storage, and waste streams are all potential odor sources</u>. Control of these odors may be achieved by scrubbing exhaust fumes and, if necessary, incinerating the remaining volatile organic compounds (VOC).

In §6.8.3.2 it is also stated (emphasis added):

In addition to particulate emissions, volatile organics may be emitted when the slurry contains organic materials with low vapor pressures. The VOCs originate primarily from the surfactants included in the slurry. The amount vaporized depends on many variables such as tower temperature and the volatility of organics used in the slurry. These vaporized organic materials condense in the tower exhaust airstream into droplets or particles. Paraffin alcohols and amides in the exhaust stream can result in a highly visible plume that persists after the condensed water vapor plume has dissipated.

Opacity and the organic emissions are influenced by granule temperature and moisture at the end of drying, temperature profiles in the dryer, and formulation of the slurry. A method for controlling visible emissions would be to remove offending organic compounds (i.e., by substitution) from the slurry. Otherwise, tower production rate may be reduced thereby reducing air inlet temperatures and exhaust temperatures. Lowering production rate will also reduce organic emissions.

It is quite clear from the teachings of Method AP-42 that <u>process system</u> temperatures are a major causal factor in the amount of VOCs released into the atmosphere. Furthermore, fluid bed dryers (from Legros *et al.*), drying towers, vent lines, vacuum exhausts, and waste streams are all regions within a process system whose temperature can be measured.

¹ EPA Method AP-42 refers to odors as VOCs.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of the admitted prior art with the teachings of Robbins, Legros et al., Masterton et al., and EPA Method AP-42 in order to provide a sample of material produced in a process system such as a fluid bed dryer, seal the material in an enclosed bag in order to have a headspace, holding the material at the mean exit temperature of the emissions of the fluid bed dryer in order to allow the headspace to come to equilibrium, and then testing for the presence of VOCs using techniques such as an FID.

First, sampling from a fluid bed dryer would have been obvious since the applicant admits that virtually every manufacturing facility worldwide must monitor for VOCs, and Legros *et al.* teaches that fluid bed dryers are a known source of VOCs. Furthermore, replicating the conditions of the process that creates VOC-containing products; i.e., replicating the temperatures at which VOC-containing products are manufactured or processed would allow one to determine if the process was indeed causing excessive VOCs to be released into the atmosphere. Finally, Robbins teaches a low-cost, simple method and apparatus for detecting VOCs in relatively small samples. One would certainly look to the teachings of Robbins in order to implement an ongoing sampling process that reduces expenses and is also relatively simple to perform. Finally, Robbins clearly addresses this shortcoming noted in the applicant's admitted prior art; i.e., Robbins clearly shows an inexpensive, less time-consuming process for conveniently measuring VOCs.

With regard to claim 3 the only difference between this claim and claim 2 is the replacement of the term "fluid bed dryer" with "spray bed dryer" as the source of the sampled material. Again, the admitted prior art teaches that virtually every unit operation in every manufacturing facility throughout the world monitors for VOC emissions. Furthermore, EPA Method AP-42 states in §6.8.3.1 that spray bed dryers are a known source of VOCs. One of ordinary skill would be motivated and, more than likely, legally required obtain samples from the spray bed drying process in order to determine the amount of VOCs being released.

With regard to claim 6 the only difference between this claim and claim 2 or 3 is the replacement of the term "fluid bed dryer" or "spray bed dryer" with "storage tank" as the source of the sampled material. Again, the admitted prior art teaches that virtually every unit operation in every manufacturing facility throughout the world monitors for VOC emissions. Furthermore, EPA Method AP-42 states in §6.8.3.1 that product storage areas; e.g., storage tanks, are a known source of VOCs. One of ordinary skill would be motivated and, more than likely, legally required obtain samples from the storage tank process in order to determine the amount of VOCs being released.

With regard to claim 4 Robbins teaches that time is a relevant factor to reach the desired equilibrium in the headspace (column 4, lines 57-58). One of ordinary skill would know to store the material in the enclosed bag for a time sufficient to reach equilibrium as this would produce a VOC concentration in the headspace that is representative of actual process system operation. The

applicant has not providing any evidence, either in the specification or in any response to any office action, that their claimed storage time produces an unexpected or unobvious result over the teachings of the prior art. See *In re Woodruff*, 919 F.2d 1575, 1578 [16 USPQ2d 1934] (Fed. Cir. 1990) ((where "the difference between the claimed invention and the prior art is some range or other variable within the claims..., the [patentee] must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results) and (Courts have long held ... that even though [a] modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art, unless the claimed ranges "produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art." (quoting *In re Aller*, 220 F.2d 454, 456 [105 USPQ 233] (C.C.P.A. 1955)))).

With regard to claim 5 Robbins teaches that the initial mass of the sample is directly related to the measured equilibrium headspace concentration (equation 5, equation 7). One of ordinary skill would know to provide a representative sample size from the process system necessary for reaching equilibrium in the headspace so that the VOC concentration is representative of actual process system operation. See again *In re Woodruff*.

With regard to claim 7 one of ordinary skill would choose a temperature that is representative of the specific operating conditions of the process system; e.g., spray bed dryer, fluid bed dryer, storage tank, etc., that is producing

VOCs so that the headspace VOC concentration is representative of actual process system operation. See again *In re Woodruff*.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

"Manual for the Certification of Laboratories Analyzing Drinking Water - EPA 815-B-97-001" to the EPA teaches that certified sampling processes require the need for instructions with a kit used for sampling of VOCs. On page IV-3, §5 it is stated:

"All procedural steps in these methods are considered requirements"

Furthermore, §6 states:

"The manner in which samples are collected and handled is critical to obtaining valid data. It is important that a written sampling protocol with specific sampling instructions be available to and used by sample collectors and available for inspection by the certification officer."

and

"The sample collector should be trained in sampling procedures and have complete written sampling instructions (SOPs) for each type of sample to be collected."

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Rogers whose telephone number is (571) 272-2205. The examiner can normally be reached on Monday - Friday (0730 - 1600). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

14 June 2006

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800